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Mail Stop Amendment
Confirmation No. 7630

In re application of : Hyun-Ah KANG et al. Attorney Docket No. P26459

Serial No. : 10/518,377 Group Art Unit : 1656
(U.S. National Stage of PCT/KR03/001279)

Filed : December 28, 2006 Examiner : William Moore

For : POLYMORPHA YAPSIN DEFICIENT MUTANT STRAIN AND PROCESS FOR THE PREPARATION OF RECOMBINANT PROTEINS USING THE SAME

Mail Stop Amendment
Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314
Sir

Transmitted herewith is a **Response to restriction requirement** in the above-captioned application.

___ Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a previously filed statement.
___ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
___ An Information Disclosure Statement, PTO Form 1449, and references cited.
___ A Request for Extension of Time.
_X_ No additional fee is required.

The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims: 17	*20	0	X25=	$	x 50=	$0.00
Indep. Claims: 3	**3	0	X100=	$	X200=	$0.00
Multiple Dependent Claims Presented			+180=	$	+360=	$0.00
Extension Fees for ___ Month(s)				$		$0.00
* If less than 20, write 20 ** If less than 3, write 3			Total:	$	Total:	$0.00

___ Please charge my Deposit Account No. 19-0089 in the amount of $_____.
_X_ A Check in the amount of $_____ to cover the filing/extension fee is included.
_X_ The U.S. Patent and Trademark Office is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.
_X_ Any additional filing fees required under 37 C.F.R. 1.16.
_X_ Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 CFR 1.136)(a)(3).

Sean Myers Pyon

Bruce H. Bernstein
Reg. No. 29,027 42,920

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Hyun-Ah KANG et al.

Group Art Unit: 1656

Appl. No. : 10/518,377
(U.S. National Stage of PCT/KR03/001279)

I.A. Filed : June 28, 2003

Examiner: William Moore

For : HANSENULA POLYMORPHA YAPSIN DEFICIENT MUTANT STRAIN AND PROCESS FOR THE PREPARATION OF RECOMBINANT PROTEINS USING THE SAME

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This is in response to the requirement for restriction under 35 U.S.C. 121 and 372 mailed from the U.S. Patent and Trademark Office on November 6, 2006, which sets a one-month shortened statutory period for response, ending December 6, 2006.

Applicants note that this response is being filed by the initial due date for response whereby an extension of time and the government fee associated therewith should not be necessary for maintaining the pendency of the application. However, if any extension of time is required to maintain the pendency of this application, this is an express request for any required extension of time and authorization to charge any necessary fee to Deposit Account No. 19-0089.

RESTRICTION

The Office restricts examination to one of the following inventions under 35 U.S.C. 121 and 372:

I. Claims 1-4, allegedly drawn to a polynucleotide encoding the *Hansenula polymorpha* protease yapsin1 having the amino acid sequence set forth in SEQ ID NO:2, and to the encoded protease yapsin1.

II. Claim 5, allegedly drawn to the amino-terminal fragment of the amino acid sequence set forth in SEQ ID NO:2 that serves as a secretion signal peptide.

III. Claims 6-17, allegedly drawn to at least three species of *Hansenula polymorpha* strains modified by deletion or disruption of a chromosomal polynucleotide region encoding the *Hansenula polymorpha* protease yapsin1 and to methods of use of each of the species in the recombinant expression of a transforming polynucleotide encoding a heterologous polypeptide.

The Office further restricts the examination of Group III to one of the following species under PCT Rule 13.1:

A. The *H. polymorpha* hpyps1△-pMOXhPTH strain of Accession No. KCTC 10282BP;

B. The *H. polymorpha* hpyps1△-YHSA12 strain of Accession No. KCTC 10283BP; and

C. The *H. polymorpha* hpyps1△-TIMP2 strain of Accession No. KCTC 10284BP.

ELECTION

In order to be responsive to the requirement for restriction, Applicants elect the invention set forth in Group III, claims 6-17, and, within Group III, the claims concerning the species set forth in (A), directed to *H. polymorpha* hpyps1△-pMOXhPTH strain of Accession No. KCTC 10282BP, with traverse. At least claims 6-9 and 12-15 are readable on the elected species.

For the reasons set forth below, Applicants respectfully submit that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

TRAVERSE

Notwithstanding the election of the claims of Group III and species (A) in order to be responsive to the requirement for restriction, Applicants respectfully traverse the requirement.

Applicants' traversal is based upon the fact that the Restriction Requirement fails to satisfy the requirements for supporting a restriction requirement under the PCT Rules. PCT Rules 13.1 and 13.2 state that an international application must relate to one invention only or, if there is more than one invention, those inventions must be so linked as to form a single general inventive concept (Rule 13.1). Inventions are considered linked so as to form a single general inventive concept only when there is a technical relationship

involving one or more of the same or corresponding "special technical features." The expression "special technical features" means those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art (Rule 13.2).

Additionally, Applicants respectfully note that Annex B to the PCT Rules states:

> **(c) Independent and Dependent Claims.** Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).
>
> (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. Equally, no problem arises in the case of a genus/species situation where the genus claim avoids the prior art. Moreover, no problem arises in the case of a combination/subcombination situation where the subcombination claim avoids the prior art and the combination claim includes all the features of the subcombination.

Unity of invention requires that the claims be considered as a whole, that a shared special technical feature be identified in all of the claims (not each individually), and that a consideration be made of the contribution that said "special technical feature" makes over the art. If the claims share a special technical feature that defines over the art, then unity of invention is present.

In the Restriction Requirement, the Office argues that the Groups lack a corresponding special technical feature, and ends the analysis at that point. Applicants respectfully submit that this is a misapplication of the unity of invention rules. The Office fails to identify a shared technical feature between the claims and consider how that feature defines over the art. Rather, the Office has focused on specifically recited elements of the claims that have different structures, and then concluded without more, that unity of invention is necessarily lacking. This analysis misapplies the proper test and therefore, the restriction of the claims into Groups I-III is improper.

Additionally, Applicants note that the Office requires an election of species, wherein the species are recited in dependent claims 9, 10, and 11. Applicants wish to emphasize that claims 9-11 are *dependent* claims, which the Annex to the PCT Rules specifically advises cannot be considered for unity of invention purposes. The Restriction Requirement is improper for this reason alone. Applicants also respectfully note that the Restriction Requirement describes the relationship between the identified Species and the remaining claims as genus/species, yet fails to show or explain how the generic claims related to the art. Again, as noted in the Annex above, "no problem arises in the case of a genus/species situation where the genus claim avoids the prior art." Applicants respectfully submit that it is improper to make a species-based restriction requirement under

unity-of-invention rules, without addressing how the generic claims relate to the art. The Restriction Requirement is improper for this reason as well.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the requirement for restriction is improper, and the requirement should be withdrawn. Withdrawal of the requirement for the restriction with examination of all pending claims is respectfully requested. Favorable consideration with early allowance of all of the pending claims is most earnestly requested.

If there are any comments or questions, the undersigned may be contacted at the below-listed telephone number.

Respectfully Submitted,
Hyun-Ah KANG et al.

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December 5, 2006
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